Declaration of James J. Lah, M.D., Ph.D.

1. I am currently an Associate Professor of Neurology at Emory University, where I also serve as Director of Emory's Cognitive Neurology Program, Vice Chair of Neurology, and Clinical Core Leader of the NIH-funded Emory Alzheimer's Disease Research Center. Since 2009, I have held the Alice and Roy Richards Endowed Chair for Alzheimer's Disease.

2. Concurrently, I serve as a member of several key committees for the Emory School of Medicine, the National Institute of Health, and the American Federation for Aging Research.

3. I received my B.S. with honors from Duke University, and earned my M.D.-Ph.D. from Ohio State University in 1992. I completed an internship in Medicine and a residency in Neurology at Emory from 1992 to 1996. At the end of my clinical training, I was awarded a Clinical Investigator Development Award from the National Institutes of Health and joined the Emory Neurology faculty.

4. I have focused my career on basic laboratory research efforts and the development of a multidisciplinary team devoted to the care of patients with Alzheimer's and other degenerative brain diseases. I am engaged in both research and in the clinical care of patients, particularly those suffering from Alzheimer's disease.

5. In the course of my work, I have become familiar with the medications that are directed at the treatment of Alzheimer's disease. Currently, there are five drugs that the FDA has approved to treat Alzheimer's disease. The drugs are Aricept, Cognex, Exelon, Namenda, and Razadyne.

6. Four of the five drugs – Aricept, Cognex, Exelon, and Razadyne – belong to the same class of drugs and work in essentially the same manner. These four are known as

cholinesterase inhibitors ("CIs"). In layman's terms, these drugs reduce the breakdown in the brain of a chemical called acetylcholine, a chemical messenger that transmits information between nerve cells. As the disease progresses, the efficacy of this class of drugs decreases. Accordingly, CIs are most often prescribed for mild to moderate Alzheimer's disease.

7. Namenda works differently. It is an NMDA antagonist. It is the only drug in its class. To the best of my knowledge, there are no therapeutic substitutes for Namenda currently on the market.

8. In layman's terms, Namenda thwarts the overstimulation of glutamate, an amino acid that excites nerves, and in excess, is a powerful nerve-cell killer. Excessive glutamate activity in mid-stage and late-stage Alzheimer's patients is believed to interfere with neurotransmission, contributing to neurodegeneration.

9. Namenda is most often prescribed for moderate through late-stage Alzheimer's.

10. I typically begin therapy with a CI, and then add Namenda as the disease progresses. Almost all of my patients who take Namenda also take a CI. The two drugs are not interchangeable; rather, they seem to have the greatest beneficial effect when they are used together.

11. I do not change or add a medication if an Alzheimer's patient seems to be doing well on the medication that he or she is currently taking.

12. None of the Alzheimer's drugs (the CIs and Namenda) alter the final outcome of the disease. I prescribe these drugs to keep patients functioning at the optimum level for them.

13. Until Forest Labs launched Namenda XR (extended release) in the summer of 2013, the only form of Namenda on the market was Namenda IR (immediate release). Namenda IR has been available in 5- and 10-mg tablets since January 2004, and in a liquid form (Namenda

Oral Solution) since August 2005. Namenda IR tablets and Namenda Oral Solution are supposed to be taken twice a day.

14. I have been prescribing Namenda IR since it became available on the market. Typically, I start patients on Namenda with a regimen of 5-mg tablets, taken once a day, escalating them over four weeks to 10-mg tablets twice a day, for a total of 20 mg daily. This is the standard way to introduce patients to Namenda treatments and titration kits are used to make this process convenient.

15. In my experience, compliance has not been a problem. A twice-daily regimen is easy to follow, as opposed to a drug regimen that requires a patient to take a drug 3 or 4 times daily.

16. I generally write 90-day Namenda IR prescriptions, with up to one year of refills.

17. I have never prescribed Namenda oral solution, only tablets. In my experience, patients and their caregivers tend to prefer tablets to the oral solution.

18. To my knowledge, Namenda oral solution is rarely prescribed. It is difficult to administer, as it must be squirted into a patient's mouth with a syringe, and dosing is less reliable.

19. Swallowing may be a problem for patients in the late stages of Alzheimer's disease, and a liquid form of a medication may be easier to swallow at that stage than a tablet (or capsule). But typically, when a patient reaches that late stage of Alzheimer's, and has difficulty taking medicines, all medications are stopped as the benefits are negligible.

20. Tablets may be crushed and sprinkled on applesauce or other soft food if a patient has difficulty swallowing a tablet. Likewise, capsules may be broken open and sprinkled on applesauce or other soft food if a patient has difficulty swallowing a capsule.

21. To the best of my recollection, Forest launched Namenda XR in June 2013. Namenda XR is sold in capsule form in 7-, 14-, 21-, and 28-mg doses. As with Namenda IR, I would start a patient on a low dose of Namenda XR and increase the dose over time. Namenda XR is administered once per day.

22. Namenda XR, because it only has to be taken once a day, may be preferred by some patients or caregivers. However, as explained below, absent a patient request, I would not switch an Alzheimer's patient who is doing well on a drug that is taken twice daily to an extended release form of the same drug, unless there is a medical reason for doing so.

23. In approximately February 2014, I received a letter from Forest that said that Forest was planning to discontinue Namenda IR as of August 15, 2014. They have, in effect, dictated to all clinicians that we must prescribe a new drug, Namenda XR, to patients who are doing well on the immediate release form of Namenda.

24. For Alzheimer's patients, stability is key: this is a very vulnerable group of patients. Any small change in medication raises the risk of an adverse effect. As Namenda is typically prescribed in the mid to later phases of Alzheimer's disease, the patients taking Namenda are at a stage in the disease when they are especially vulnerable. Even a small change in a patient's condition can require him or her to be moved to a care facility.

25. Forest's action forces us to violate the common sense rule that Alzheimer's patients should not be switched from one drug to another if the first drug is working well for them, absent evidence that the second drug offers significant therapeutic benefits that the first drug does not.

26. While Namenda is of modest effectiveness in alleviating symptoms suffered by Alzheimer's patients, it does offer some clinical benefits and is an important option in our

currently limited set of options. For those individuals without adequate prescription drug coverage (for example, patients who are uninsured, or who have plans with high deductibles or co-pays), monthly costs for Namenda can exceed $500 per month, making the drug effectively unavailable for many of these individuals.

27. In my experience, generic drugs cost less than the brand versions to which they are related. When generic versions of Namenda IR (memantine) become available, the drug may be more accessible to patients, especially those who have declined to use it due to the cost of the branded version. Even patients who currently use Namenda would benefit from generic Namenda as it is my understanding that most insurance plans charge lower co-pays for generics than for branded drugs.

28. I understand that the FDA has approved Forest's application for six months of pediatric exclusivity for Namenda IR, and that as a result, the first generic versions of the drug will not be marketed until July 2015.

29. Recently, I learned that Forest now plans to discontinue Namenda IR in the fall of 2014, as opposed to the originally announced date of August 15, 2014. Regardless, I and other physicians will be forced to switch patients who are doing well on Namenda IR to Namenda XR without any medical reason for doing so, and with the risk that it may have an adverse effect on this very vulnerable class of patients. Neither we nor our patients will have a choice: there will be no version of Namenda IR on the market—neither brand nor generic. Until at least July 2015, the only version of Namenda, and indeed, the only drug available in this class of drug, will be Namenda XR.

30. Moreover, by forcing a switch to Namenda XR, Forest also has created the risk that some of these vulnerable patients will need to have their medication switched twice – first,

from branded IR to XR, and then back from XR to IR after generics enter the market. In particular, patients who have been forced to switch to XR but who, because of their insurance coverage or for other reasons, must switch back to the IR to reduce costs, will be forced to undergo this process twice.

31. In many cases, I may not switch patients back unless they specifically request that I do so, because, as stated above, switching Alzheimer's patients may trigger adverse effects.

32. Moreover, in my experience, patients very rarely specifically request that I prescribe them generic drugs instead of brand-name drugs. In addition, while branded drug manufacturers like Forest typically market their drugs so that I have a good sense of when they are available, I generally don't receive marketing from generic manufacturers, and would have to undertake my own efforts to learn when a product like generic Namenda is about to become available.

33. I know of no published data regarding potential adverse effects that may result from switching patients from immediate release to extended release versions of Namenda, or regarding potential adverse effects of switching from extended release to immediate release versions of the drug.

34. As explained above, switching Alzheimer's patients from one drug to another without any medical reason for doing so is inconsistent with my best professional judgment in the treatment of Alzheimer's patients.

35. If Forest continues to sell Namenda IR along with Namenda XR, I and other physicians will have the choice of which formulation to prescribe, depending on what is best for each patient that we treat after taking into account the medical, clinical, and financial advantages and disadvantages for each of our patients. But if Forest implements its plan to cease selling

Namenda IR, then I will have no choice but to switch my patients using Namenda IR to Namenda XR (or take them off of the medication entirely). In my opinion, Forest's actions are not in the best interests of Alzheimer's patients and doctors, and risk harming the very patients who are supposed to be benefiting from the pharmaceuticals that Forest markets.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on September 8, 2014.

James J. Lah, M.D., Ph.D.